UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

KARIN FUSSY, Plaintiff, v. RTI SURGICAL, Defendant.	No. 1:21-cv-01307-DAD-BAK ORDER GRANTING DEFENDANT'S MOTION TO DISMISS (Doc. No. 4)

This matter is before the court on defendant RTI Surgical's motion to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6). (Doc. No. 4.) Pursuant to General Order No. 617 addressing the public health emergency posed by the COVID-19 pandemic, defendant's motion was taken under submission on the papers. (Doc. No. 6.) For the reasons explained below, the court will grant defendant's motion to dismiss.[1]

[1] The undersigned apologizes for the excessive delay in the issuance of this order. This court's overwhelming caseload has been well publicized and the long-standing lack of judicial resources in this district long-ago reached crisis proportion. That situation has now been partially addressed by the U.S. Senate's confirmation of a district judge for one of this court's vacancies on December 17, 2021. Nonetheless, for over twenty-two months the undersigned was left presiding over approximately 1,300 civil cases and criminal matters involving 735 defendants. That situation resulted in the court not being able to issue orders in submitted civil matters within an acceptable period of time and continues even now as the undersigned works through the predictable backlog. This has been frustrating to the court, which fully realizes how incredibly frustrating it is to the parties and their counsel.

BACKGROUND

On March 17, 2021, plaintiff Karin Fussy, who is proceeding *pro se* in this products liability action, filed her complaint initiating this case against defendant RTI Surgical in the Kern County Superior Court. (Doc. No. 1-1 at 2.) On August 27, 2021, defendant removed the action to this federal court based on diversity jurisdiction under 28 U.S.C. § 1332. (Doc. No. 1.)

Plaintiff alleges as follows in her complaint. On January 20, 2012, plaintiff underwent a lumbar spine fusion. (Doc. No. 1-1 at 11.) During this operation, the assigned surgeon used "Pioneer Pedicle Screws" to hold plaintiff's spine in position while the fusion took place. (*Id.*) Although not explicitly stated in the complaint, plaintiff appears to allege that the screws used for her surgery are manufactured by defendant. In the eight years following her operation, plaintiff attended many appointments with doctors after complaining of pain, but she was told that nothing was wrong. (*Id.*) Throughout that time, plaintiff's pain in her back increased and her ability to walk and talk deteriorated. (*Id.*) During an emergency visit to a hospital in October 2019, an emergency room doctor allegedly told plaintiff that she should get the screws removed because they were "impeding on [her] spine." (*Id.*)

On February 24, 2020, "the apparatus was removed by Dr. Wang of USC." (*Id.*) Plaintiff alleges that as soon as the screws were removed, she no longer suffered from any pain. (*Id.*) ("The very next day and ever since I have not had a single bit of pain. I am off all pain medication and blood pressure medication.") According to plaintiff, "[i]t is clear to say that the screws moving and impeding into my spine is what caused the damage to my back and the pain I experienced." (*Id.* at 12.) Plaintiff alleges that as a result of nerve damage supposedly caused by the screws used in her spine fusion surgery, she has trouble walking, experiences muscle cramps, has vocal trouble, and falls down a lot. (*Id.*) Based on the forgoing, plaintiff alleges causes of action for strict product liability and negligent product liability. (*Id.* at 5.)

On September 2, 2021, defendant filed a motion to dismiss all of plaintiff's claims. (Doc. No. 4.) Plaintiff failed to timely file an opposition to defendant's motion. However, on November 17, 2021, plaintiff filed her untimely opposition to defendant's motion to dismiss. (Doc. No. 16.) Defendant did not file a reply to plaintiff's opposition.

LEGAL STANDARD

The purpose of a motion to dismiss pursuant to Rule 12(b)(6) is to test the legal sufficiency of the complaint. *N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983). "Dismissal can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A claim for relief must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Though Rule 8(a) does not require detailed factual allegations, a plaintiff is required to allege "enough facts to state a claim for relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. In determining whether a complaint states a claim on which relief may be granted, the court accepts as true the allegations in the complaint and construes the allegations in the light most favorable to the plaintiff. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984); *Love v. United States*, 915 F.2d 1242, 1245 (9th Cir. 1989). It is inappropriate to assume that the plaintiff "can prove facts that it has not alleged or that the defendants have violated the . . . laws in ways that have not been alleged." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983).

"Dismissal without leave to amend is proper if it is clear that the complaint could not be saved by amendment." *Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1051 (9th Cir. 2008). To the extent that the pleadings can be cured by the allegation of additional facts, courts will generally grant leave to amend. *Cook, Perkiss and Liehe, Inc. v. N. Cal. Collection Serv. Inc.*, 911 F.2d 242, 247 (9th Cir. 1990) (citations omitted).

DISCUSSION

Based on plaintiff's complaint, it is not entirely clear which theory of product liability she is attempting to pursue in this action. California recognizes strict liability for three types of product defects—manufacturing defects, design defects, and warning defects (inadequate warnings or failure to warn). *Anderson v. Owens–Corning Fiberglas Co.*, 53 Cal. 3d 987, 995

(1991); *Karlsson v. Ford Motor Co.*, 140 Cal. App. 4th 1202, 1208 (2006). In various sections of her complaint and in her opposition brief, plaintiff alludes to each of these theories, as well as to a negligence theory of product liability. Accordingly, out of an abundance of caution, the court will conduct a short analysis with regard to each of the three separate theories of liability that can support a strict product liability claim under California law. The court will then briefly address any potential negligence claim that plaintiff may be attempting to bring as well.

A. Manufacturing Defect

Under California law, a manufacturing defect "is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *Barker v. Lull*, 20 Cal. 3d 413, 429 (1978). The manufacturing defect theory posits that "a suitable design is in place, but that the manufacturing process has in some way deviated from that design." *In re Coordinated Latex Glove Litig.*, 99 Cal. App. 4th 594, 613 (2002).

In her complaint, plaintiff has not listed any allegations to support a manufacturing defect claim. If plaintiff intends to allege a manufacturing defect, she must state allegations identifying and explaining how the pedicle screws either deviated from defendant's intended result/design or how the screws deviated from other identical products. *See Barker*, 20 Cal. 3d at 429. Plaintiff has not done so in her complaint and indeed appears to concede in her opposition to the pending motion that she "did not allege that the pedicle screws [] used by the plaintiff's physician in her fusion procedure differed from RTI's intended design." (Doc. No. 16 at 4.) Accordingly, the court will grant defendant's motion to dismiss plaintiff's strict product liability claim to the extent it is predicated on an alleged manufacturing defect.

B. Design Defect

To be actionable under the design defect theory of product liability, a product design must be defective in one of two ways. *Soule v. Gen. Motors Corp.*, 8 Cal. 4th 548, 566–67 (1994); *Karlsson*, 140 Cal. App.4th at 1208. First, under the "consumer expectation test," a product's design is defective if it has failed to perform as safely as its ordinary consumers would expect when used in an intended or reasonably foreseeable manner. *Barker*, 20 Cal. 3d at 413. Second,

under the "risk-benefit test," a product's design is defective if the design embodies "excessive preventable danger," that is, the risk of danger inherent in the design outweighs the benefits of such design. *Id.* at 430; *Ford v. Polaris Indus., Inc.*, 139 Cal. App. 4th 755, 766 (2006). "The two tests provide alternative means for a plaintiff to prove design defect and do not serve as defenses to one another." *McCabe v. Am. Hondo Motor Co., Inc.*, 100 Cal. App. 4th 1111, 1121 (2002). Moreover, particularly relevant here, California law precludes strict liability predicated on design defects with respect to manufacturers of prescription medical devices, including implanted devices such as the screws at issue in this case. *See Garrett v. Howmedica Osteonics Corp.*, 214 Cal. App. 4th 173, 182 (2013) (recognizing "an exemption from design defect strict products liability for all implanted medical devices that are available only through the services of a physician"). Rather, under California law, "the appropriate test for determining a prescription [medical device] manufacturer's liability for a design defect involves an application of the ordinary negligence standard." *Id.* Under the negligence standard . . . , a manufacturer is liable for a design defect only if it failed to warn of a defect that it either knew or should have known existed." *Id.*

As with plaintiff's manufacturing defect claim, dismissal of any design defect claim is appropriate here because plaintiff's complaint contains no factual allegations identifying what aspect of the pedicle screws' design made them defective or how defendant failed to warn about said defect. Accordingly, the court will likewise grant defendant's motion to dismiss plaintiff's strict product liability claim to the extent it is predicated on an alleged design defect.

C. Failure to Warn

Because a manufacturer generally has a duty to warn consumers about the hazards of its product, a product may be dangerous because it lacks adequate warnings or instructions. *Webb v. Special Elec. Co. Inc.*, 63 Cal. 4th 167, 180–81 (2016). Under California law, a failure-to-warn claim may be brought under either a theory of negligence or a theory of strict liability. *Hannan v. Boston Sci. Corp.*, No. 19-cv-08453-PJH, 2020 WL 2128841, at *6 (N.D. Cal. May 6, 2020). Although not entirely clear, it appears that plaintiff's failure to warn claim may be rooted in strict liability. Manufacturers are strictly liable for injuries caused by their failure to provide adequate

warnings of known or reasonably scientifically knowable dangers at the time they manufactured and distributed their product. *Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 64 (2008); *Carlin v. Superior Ct.*, 13 Cal.4th 1104, 1108–09 (1996). "A plausible claim for a failure to warn should include allegations that *inter alia* identify which danger was not warned against, explain that the danger was substantial, and that the danger was known or reasonably knowable, or explain how any warning that was given was inadequate." *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1161-62 (E.D. Cal. 2019) (citing *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1156 n.1 (E.D. Cal. 2010)).

Furthermore, although California law permits a strict liability failure to warn theory of liability, it also provides that failure to warn in the prescription medical devices context must be read in tandem with California's "learned intermediary" doctrine. *Hannan*, 2020 WL 2128841, at *7; *Bigler-Engler v. Breg, Inc.*, 7 Cal. App. 5th 276, 319 (2017) (noting that the learned intermediary doctrine applies to implanted medical devices). The learned intermediary doctrine states that in the case of prescription drugs and medical devices, the duty to warn "runs to the physician, not the patient." *Id.* (citing *Carlin*, 13 Cal. 4th at 1116); *see also Webb*, 63 Cal. 4th at 187 n.10. A manufacturer discharges this duty to warn by "provid[ing] adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient." *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 990–91 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659 (9th Cir. 2004). The learned intermediary doctrine "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship[,]" *Webb*, 63 Cal. 4th at 187 n.10, but "does not apply to medical devices . . . which require the patient to use and apply the medical device themselves." *Bigler-Engler*, 7 Cal. App. 5th at 319. Where the doctrine applies, a plaintiff who asserts a claim "based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017).

As an initial matter, nowhere in her complaint in this action does plaintiff allege that defendant failed to adequately warn her about the potential risks of her procedure. Specifically,

plaintiff omits any mention of what danger she should have been warned against, how that danger was substantial, or in what capacity defendant knew about that danger. Furthermore, the sparse allegations of plaintiff's complaint appear to suggest that a physician prescribed the lumbar spine fusion plaintiff received and also prescribed using defendant's pedicle screws to hold plaintiff's spine in place. (*See* Doc. No. 1-1 at 11) ("During the surgery, the surgeon (Dr. Watkins of Watkins Spine Center) used Pioneer Pedicle Screws to hold the spine in place while the fusion took place."). As such, the learned intermediary doctrine would appear to apply to plaintiff's failure to warn claim, which arises from injuries allegedly caused by defendant's medical device. *See Riera v. Mecta Corp*, No. 2:17-cv-06686-RGK-JC, 2021 WL 2024688, at *4 (C.D. Cal. May 14, 2021) ("Because [plaintiffs] were treated with the Thymatron System IV by their doctors in a hospital setting, the learned intermediary doctrine applies."). Therefore, to successfully allege a failure to warn claim here, plaintiff must allege facts sufficient to show that: (1) defendant did not warn plaintiff's doctors of the risks associated with the pedicle screws "or the warning was inadequate," and (2) "that the inadequacy or absence of the warning caused" plaintiff's injuries. *Wendell*, 858 F.3d at 1238 (citation omitted). Having failed to allege any such facts, plaintiff has not adequately alleged a failure to warn claim under California law in her complaint.

Accordingly, defendant's motion to dismiss plaintiff's failure-to-warn product liability claim will be granted.

D. Negligence

Plaintiff also appears to assert a claim for "negligence," although she does not expand on such a claim beyond that. (*See* Doc. No. 1-1 at 5.) Based on plaintiff's allegations, it appears that plaintiff may be attempting to assert a negligence product liability claim.

A negligence claim under California law requires plaintiff to allege that defendant "owed [plaintiff] a legal duty, breached the duty, and that the breach was a proximate or legal cause of [plaintiff's] injury." *Gonzalez v. Autoliv ASP, Inc.*, 154 Cal. App. 4th 780, 793 (2007). "In the context of a products liability lawsuit, '[u]nder a negligence theory, a plaintiff must also prove . . . that the defect in the product was due to negligence of the defendant.'" *Id.* (quoting *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479 (2001)) (quotations omitted).

Here, plaintiff appears to allege that the product at issue in this case was dangerous and harmed her, but she does not advance allegations explaining how the product created the alleged danger, the nature of that danger, or how that danger caused her injury. Moreover, plaintiff alleges no facts as to how defendant owed her a duty or how defendant's actions are connected to any purported defect in the product. Put simply, the allegations in the complaint fall far short of stating a cognizable cause of action for negligence. Accordingly, defendant's motion to dismiss plaintiff's negligence claim will also be granted.

E. Leave to Amend

The undersigned acknowledges that federal courts must liberally construe the "inartful pleading" of *pro se* litigants. *Eldridge v. Block*, 832 F.2d 1132, 1137 (9th Cir. 1987). Nonetheless, plaintiff has failed to sufficiently state any cognizable claim for relief, and the court will therefore dismiss her complaint in its entirety. The court will now consider whether to grant plaintiff leave to amend.

Generally, "[c]ourts are free to grant a party leave to amend whenever 'justice so requires,' and requests for leave should be granted with 'extreme liberality.'" *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 972 (9th Cir. 2009). There are several factors a district court considers in whether to grant leave to amend, including undue delay, the movant's bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party, and futility. *Brown v. Stored Value Cards, Inc.*, 953 F.3d 567, 574 (9th Cir. 2020) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

Given plaintiff's *pro se* status and the lack of any identifiable prejudice to defendant, the court will grant plaintiff leave to file an amended complaint if she is able to do so in good faith. Plaintiff is advised that the court cannot refer to a prior pleading in order to make an amended complaint complete. Local Rule 220 requires any amended complaint to be complete in itself without reference to prior pleadings. An amended complaint will supersede the original complaint. *See Loux v. Rhay*, 375 F.2d 55, 57 (9th Cir. 1967). Thus, in any amended complaint that plaintiff elects to file, she must include concise but complete factual allegations describing the conduct and events that underlie her claims. She must clearly identify her causes of action

and the legal basis for each claim, and she must attempt to cure the various deficiencies the court has identified in this order if she wishes to pursue these claims.

CONCLUSION

For the reasons set forth above, defendant's motion to dismiss (Doc. No. 4) is granted. Any amended complaint plaintiff may elect to file shall be filed within twenty-one (21) days of service of this order.

IT IS SO ORDERED.

Dated: **April 13, 2022**

UNITED STATES DISTRICT JUDGE